

## **Section 2.0 - SMDA 1990 Requirements**

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### **2.1 510(k) Summary**

#### **Device Description**

The ENDOcare Electrosurgical Electrodes are accessories that fit commercially available resectoscopes, cystoscopes, laproscopes and hysteroscopes, pencil grips and pistol grips. Each model has a different configuration which offers the surgeon a variety of tissue interaction tips depending on the specific surgical application.

#### **Biocompatibility**

The biocompatibility requirements were determined through use of the International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The ENDOcare Electrosurgical Electrode has the same material, manufacturing process, chemical composition, body contact and sterilization method as the currently marketed electrode. Therefore, per the FDA matrix, the biocompatibility requirements were met and no additional testing was performed.

#### **Substantial Equivalence Support**

The ENDOcare Electrosurgical Electrodes are designed for use in general surgery, urology, gynecology and orthopedics for cutting, coagulation, resection and vaporization of tissue including BPH (Benign Prostatic Hyperplasia), tumors, fibroids, cysts and obstructive tissue. The ENDOcare Electrosurgical Electrodes are substantially equivalent to the ENDOcare Electrosurgical Electrodes (reference K954321) which were found to be substantially equivalent to the Unimed Electrodes (reference K944540 and K945191) on October 13, 1995.

#### **Sterilization Methodology**

This electrode may be shipped as a non-sterile, reusable device. The following are the recommended cleaning and sterilization instructions:

##### **(1) Cleaning**

- Wipe all debris from the electrode with a moistened sponge or gauze pad.
- Rinse with cold tap water for approximately 30 seconds.
- Place the electrode in a warm bath of tap water and detergent and scrub with the appropriate brush, taking care to keep the electrode totally immersed at all times.

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- Rinse with warm tap water for approximately 20 seconds to remove any debris or detergent. If necessary, place in an ultrasonic bath containing sonic detergent for 10 minutes at 60 hz. Remove and rinse with tap water for approximately 20 seconds.
- Rough dry.

(2) Sterilization

- Check the electrode for particulate contamination. If necessary, wipe down the electrode with a clean gauze pad.
- Wrap the electrode in sterilization wrap using a standard hospital square wrap.
- Autoclave in a pre-vacuum cycle using the following parameters:

Exposure Temperature	132°C
Exposure Time	8 minutes
Pressure	42 to 44 PSIA
Dry Time	5 minutes